PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to prescription drug donation repository program and providing an opportunity for public comment

The Public Health Department hereby proposes to amend Chapter 109, "Prescription Drug Donation Repository Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapter 135M.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 135M.

Purpose and Summary

These proposed amendments will update outdated citations within Chapter 109 and address an unintentional issue that occurred from some new wording in different legislation that was not intended to apply to the program covered by Chapter 108. The Department provided a waiver in 2019 to address the situation. The proposed amendment to the definition of "centralized repository" in Item 1 is a permanent solution that will remove the need for the waiver. Other amendments remove references to repealed Iowa Code chapters and a rescinded rule and update an Iowa Code citation.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on December 7, 2021. Comments should be directed to:

Susan Dixon Department of Public Health 321 East 12th Street Des Moines, Iowa 50319

Email: susan.dixon@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental

subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule **641—109.1(135M)**, definitions of "Centralized repository" and "Physician," as follows:

"Centralized repository" means a distributor an entity approved by the contractor and licensed pursuant to 657 IAC Chapter 17 applicable regulations of the Iowa board of pharmacy that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, rules and regulations.

"Physician" means an individual licensed under Iowa Code chapter 148, 150, or 150A.

ITEM 2. Amend subrule 109.5(3) as follows:

109.5(3) Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to board of pharmacy rule 657—8.8(124,155A) 657—subrule 8.7(5). The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.5(4).

ITEM 3. Amend subrule 109.14(1) as follows:

109.14(1) The department may receive prescription drugs and supplies directly from the prescription drug donation repository contractor and dispense prescription drugs and supplies through licensed personnel during or in preparation for a disaster emergency proclaimed by the governor pursuant to Iowa Code section 29C.6 or during or in preparation for a public health disaster as defined in 2009 Iowa Code Supplement section 135.140, subsection 6 135.140(6).